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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,429	08/07/2006	Norihiro Nishimoto	053466-0417	6508

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EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
03/22/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,429	NISHIMOTO ET AL.	
	Examiner	Art Unit	
	MARIANNE P. ALLEN	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2012*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *29-42* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☒ Claim(s) *29,31,35-39,41 and 42* is/are allowed.

7)☒ Claim(s) *30,32,33 and 40* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/6/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The rejection of claims 29, 31, 38, 39, and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. (U.S. Patent Number 7,320,792) in view of Hirohata et al. (1993), and Noris et al. (1999) is withdrawn.

Ito et al. teaches monoclonal antibody PM-1, an antibody against IL-6 receptor, and humanized forms thereof, for use in treatment of psoriasis, which is disclosed to be associated with elevated IL-6 levels.

Hirohata et al. teaches that polyarteritis nodosa is associated is marked elevation of CSF IL-6 activity in parallel with CNS disease activity, and showed elevation of serum IL-6 in association with systemic systems.

Noris et al. teaches that elevated IL-6 levels are associated with Takayasu arthritis, and consider such as indirect evidence that vasculitic lesions that characterize Takayasu arthritis are dependent on IL-6 producing cells and that there a close correlation between IL-6 and the disease.

However, none of these pieces of art individually or collectively suggests treating subjects with vasculitis by administering an antibody that targets the IL-6 receptor. The disclosure of Ito et al. is directed to treating psoriasis and not broader conditions. Neither Hirohata et al. or Noris et al. suggest targeting the IL-6 receptor for therapeutic intervention.

Because the only remaining art rejection has been withdrawn, the species elections set forth in the restriction requirement mailed 12/3/08 are withdrawn. Claims 30, 32, 33, 37, and 40 are hereby rejoined. Claims 29-33 and 35-42 are under consideration and have been fully considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 40 requires the MR1 antibody. The specification does not describe the structural features of this antibody or how to make it. This antibody does not appear to have been a well known or readily available antibody. This antibody does not appear to have been produced by a hybridoma that has been deposited in compliance with MPEP 2402.

This antibody is not enabled by the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30, 32, 33, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites "vasculitis having resistance to steroids and/or immunosuppressants." The specification and claim do not make what the metes and bounds of this phrase are. It is not known what is required to meet the limitation of having resistance or what level of resistance is required. It is not known whether this requires that steroids and/or immunosuppressants are currently being administered to the subject or have been administered to the subject in the past (or both). It is not known if the resistance required is indicated by some unspecified symptoms or physical manifestations.

Claim 32 recites "vasculitis is the aortitis syndrome." This language implies that the intended vasculitis is a single condition. Page 2 of the specification discloses that "The aortitis syndrome is also termed as Takayasu's arteritis." It is unclear if claim 32 is limited to Takayasu's arteritis or if it embraces other conditions or symptoms as part of a syndrome. It is unclear what conditions or symptoms "the aortitis syndrome" includes or excludes. It is assumed that this claim requires that the subject being treated has the recited aortitis syndrome.

Claim 33 recites "vasculitis is associated with immunological abnormalities." Page 2 of the specification discloses "vasculitis associated with immunological abnormalities, for example, there can be mentioned vasculitis associated with rheumatoid and vasculitis associated with systemic lupus erythematosus (SLE)." These examples are not a limiting definition and it is not clear what other immunological abnormalities associated with vasculitis are embraced by the claims. It is assumed that this claim requires that the subject being treated has the recited immunological abnormality and its associated vasculitis.

Claim 40 recites "MR1 antibody." It is not known from the specification what the structural features of this antibody are.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIANNE P. ALLEN whose telephone number is (571)272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARIANNE P ALLEN/
Primary Examiner, Art Unit 1647

mpa